ECA Academy
Your GMP/GDP Information Source

Analytical Procedure Lifecycle Management

This conference is part of
2018 PharmaLab Congress & Exhibition
Analytics•Bioanalytics•Microbiology
Düsseldorf, 20/21 November 2018
www.pharmalab-congress.com

Every participant will receive Version 01 of the Laboratory Management **Guidance Analytical Procedure Lifecycle Management** developed by the ECA Analytical Quality Control Group.

SPEAKERS FROM THE ECA ANALYTICAL QUALITY CONTROL GROUP:

DR CHRISTOPHER BURGESS
Burgess Analytical Consultancy Limited

SILVIYA DIMITROVA
TEVA Bulgaria

DR GERD JILGE
Boehringer Ingelheim Pharma

MARGARITA SABATER
Dako Denmark, an Agilent Technologies Company

A holistic Approach to Design, Development, Qualification and Control of Analytical Procedures and launch of the new ECA Guideline

20 November 2018, Düsseldorf/Neuss, Germany

HIGHLIGHTS:

- ICH Press Release: ICH agreed to begin work on ICH harmonization for Analytical Procedure Development and Revision of Q2(R1) Analytical Validation (Q2(R2)/Q14)
- Practical Advice on how to Apply Quality by Design for Analytical Methods
- Laboratory Data Management Guidance Analytical Procedure Lifecycle Management (80 pages)
- Overview of the new APLM Guideline and the APLM Workshop
- Stage 1: Procedure Design and Development
- Stage 2: Procedure Performance Qualification (PPQ)
- Stage 3: Procedure Performance Verification
- APLM Questionnaire
- Workshop Critique of a SWOT Analysis of the APLM

Media Partner:
European Biotechnology Life Sciences and Industry Magazine
EPR European Pharmaceutical Review

Analytical Procedure Lifecycle Management

20 November 2018, Düsseldorf/Neuss, Germany

Objectives & Background

The assurance of 'fitness for purpose' of analytical procedures is a critical part of any process for ensuring drug quality. Since 2011, USP's Validation and Verification Expert Panel has been considering how the modern concept of lifecycle model process validation can be applied to analytical procedures. Thus the panel has published articles and a proposal for a new General Chapter <1220> in 2017. This is under revision based upon comments received, and it is expected that a new version will be issued in 2018.

In addition, the long anticipated revision of the ICH Q2(R1) "Guideline on Validation of Analytical Procedures: Text and Methodology" has been sanctioned and the work plan is scheduled to commence in Q3 2018. It is also proposed to develop a new quality guideline on Analytical Procedure Development. It is intended that the new guidelines will be consistent with ICH Q8(R2), Q9, Q10, Q11 and Q12.

In the light of these developments ECA's Analytical Quality Control Group has developed a new Guideline on Analytical Procedure Lifecycle Management. It is consistent with the ICH and USP principles and provides detailed assistance in their practical implementation. This Guideline will be formally launched at this pre-conference workshop. And as a participant you will exclusively receive a copy. The ECA AQCG has also conducted a survey to find out more about the current status and issues regarding implementation of APLM in industry. The results and conclusions will be shared at this workshop.

Every participant will receive the current version of the ECA Laboratory Management **Guidance Analytical Procedure Lifecycle Management**.

This comprehensive (around 80 page) Guidance Document Analytical Procedure Lifecycle Management covers the following topics:

- Key References
- Quality involvement/Responsibilities
- Rationale for this Guideline
- Principles of Analytical Procedure Lifecycle Management (APLM)
- Prerequisites for the APLM
- Guidance recommendations for the 3 stages analytical procedure of the APLM
- Stage 1: Procedure Design and Development
- Procedure development and gaining understanding
- Stage 2: Procedure Performance Qualification
- Stage 3: Procedure Performance Verification
- Technical Glossary

Target Audience

The ECA Academy wish to actively involve analytical chemists, QC analysts, quality assurance associates & managers, R&D scientists, statisticians & managers as well as manufacturing scientists and managers, regulatory affairs specialists and contract laboratories in this critical area for analytical science.

Social Event

On the evening of the first congress day, on 20 November 2018, all congress delegates and speakers are invited to a „Get together" in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

Speakers

DR CHRISTOPHER BURGESS, *Burgess Analytical Consultancy Limited.* Chairman of the ECA Analytical Quality Control Group. Qualified Person in the EU. Member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters.

SILVIYA DIMITROVA , *TEVA Bulgaria.* Member of the ECA AQC Group Board and QP. Overall responsibility for quality oversight of European TEVA suppliers as well as QC and QP Release.

DR GERD JILGE, *Boehringer Ingelheim Pharma.* Quality Control. Member of the EDQM expert group 11 and Board Member of the ECA AQC Group.

MARGARITA SABATER, *Dako Denmark, an Agilent Technologies Company.* Manager Compliance Support at Dako. Board Member of the ECA AQC Group.

Programme 20 November 2018

Alternative Microbiological Methods: AstraZeneca's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap	**MIRIAM GUEST,** *AstraZeneca* **PHILIP BREUGELMANN,** *JnJ* **DR SVEN M. DEUTSCHMANN,** *Roche* 
Overview of the new APLM Guideline and the Workshop	■ Principles of Analytical Procedure Lifecycle Management (APLM) ■ Importance of adopting an APLM approach in the context of data integrity governance ■ Limitations of the current ICH Q2(R1) & USP General Chapters ■ ECA Guidelines; intent and application for laboratory data integrity ■ Content of new APLM guideline ■ Workshop intent and processes **DR CHRISTOPHER BURGESS,** *Chairman of the ECA AQCG Board*
Stage 1: Procedure Design and Development	■ Defining the Analytical Target Profile (ATP) ■ Defining the Target Measurement Uncertainty (TMU) ■ Quality by Design; Application to Analytical Procedures ■ Risk Management for Analytical Procedures ■ Defining an Analytical Control Strategy **MARGARITA SABATER ,** *ECA AQCG Board*
Stage 2: Procedure Performance Qualification (PPQ)	■ Alignments, differences and advantages to traditional ICH validation ■ General and procedure-specific performance attributes ■ Experimental confirmation in stage 2 or reference to stage 1? ■ Precision of the reportable value and replication strategy **DR GERD JILGE,** *ECA AQCG Board*
Stage 3: Procedure Performance Verification	■ Analytical Procedures as processes ■ Process stability and capability ■ Requirements for routine process monitoring of analytical procedures ■ Quality Metrics ■ What to trend and what not to trend ■ Trending as part of the analytical control strategy and confirmation of the ATP ■ Are we trying to control means or individuals? ■ Overview of trending tools for discrete and variable data **SILVIYA DIMITROVA,** *ECA AQCG Board*
APLM Questionnaire	■ Structure and intent ■ Analysis of the responses ■ Conclusions **DR CHRISTOPHER BURGESS,** *Chairman of the ECA AQCG Board*
Workshop Critique of a SWOT Analysis of the APLM	■ What is a SWOT Analysis? ■ Review of a SWOT Analysis for an APLM ■ Interactive discussion ■ Conclusions and the way forward **ALL MEMBERS OF THE ECA AQCG BOARD**
ICH Concept Paper for Revision of Q2(R2) & Q14	**DR CHRISTOPHER BURGESS,** *Chairman of the ECA AQCG Board*
Interactive discussion of the ICH implications and Questions	**ALL MEMBERS OF THE ECA AQCG BOARD**

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.pharmalab-congress.com

Dates
Tuesday, 20 November 2018, 09.00 – 18.00 h
(Registration Monday, 19 November, 19.00 – 20.30 h and
Tuesday, 20 November, 08.00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
41460 Neuss, Germany
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
emailus@cphotelduesseldorfneuss.com

Fees (per delegate plus VAT)
19 November 2018: Pre-Conference ,,1st International Mycoplasma qPCR Testing User Day" € 249,- **(fully booked up)**
20 November 2018 € 690,-
21 November 2018 € 690,-

The conference fee is payable in advance after receipt of invoice and includes lunch on that day/on both days as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day. VAT is reclaimable.

Your registration also entitles you to participate in all other PharmaLab Congress conferences during the day of your conference/during the two days. For information on all PharmaLab conferences please visit **www.pharmalab-congress.com**.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.pharmalab-congress.com

PLEASE NOTE
Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

Organisation & Contact
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Part of PharmaLab 2018, Düsseldorf/Neuss, Germany, 20-21 November 2018
☐ Conferences on 20.11.2018 – € 690,- plus VAT
☐ Conferences on 21.11.2018 – € 690,- plus VAT
I would like to attend the following conference(s):
☐ **Analytical Procedure Lifecycle Management** (20 November 2018)

☐ Yes, I will participate in the Social Event on 20 November.
☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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PLEASE NOTE: Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice!

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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